REMARKS

Information Disclosure Statement

In response to Examiner's comments relating to consideration of references listed in the specification only, Applicant submits herewith a Supplemental IDS. The Supplemental IDS comprises two references listed in the instant specification but not previously listed on PTO Form 1449. Applicant respectfully requests that the Examiner indicate that these references have been considered in prosecution of this application by so indicating on the enclosed form and returning a copy to Applicant.

Drawings

Applicant has amended the specification to reflect the proper heading for the section of the specification relating to the drawings filed with this application.

35 USC §112

The Examiner has rejected to Claim 16 and 17 as failing to comply with the written description requirement, for being indefinite, and for lacking antecedent basis under 35 USC §112. Applicant has amended Claim 16, to remove the phrase "nicotine derivatives" and to more clearly indicate that active agents may be nicotine actives, which are further defined in Claim 17. As a result of this amendment, Application respectfully requests that the Examiner withdraw the rejection.

35 USC §102

The Examiner has rejected claims 1-4, 6-8, 32 and 33 as being anticipated by US 6,290,985 to Ream et al (hereinafter "Ream"), stating that "Ream discloses composition that comprisises nictotine...guar gum hydrolysate....and isomalt". Applicant asserts that Ream does not teach or disclose each and every element of the present invention and, thus, does not anticipate the present invention.

The present invention, relates to an oral dosage form comprising a glassy matrix comprising at least one substantially non-hygroscopic sugar alcohol capable of forming a glassy structure, a water soluble gelling gum which is present in an amount sufficient to provide a desired dissolution rate of said glassy matrix, and an active agent. The glassy, amorphous, matrix acts as a carrier for the nicotine active

and any optional adjuvants and the resulting composition is orally dissolvable and useful for transmucosal delivery of the nicotine active.

In contrast, Ream relates to a chewing gum composition comprising a tabletted gum center and a coating, suitable for delivering a medicament or agent to an individual. The tabletted gum center comprises a water soluble portion and a water insoluble portion. The water soluble portion of the tabletted gum center may contain, among other components, a low caloric bulking agent such as guar gum hydrolysate and sugarless sweeteners including sugar alcohols, however, to achieve the chewing gum compositions disclosed therein a water insoluble portion of the gum center is also required. The coating comprises the medicament or agent and, preferably, a masking agent, such as isomalt. There is no teaching that the isomalt present in the Ream composition may be prepared as a glassy matrix suitable for oral dissolution, as this would clearly not render a suitable chewing gum composition. Further, as Ream does not teach a composition comprising a glassy matrix structure, it cannot be said that Ream discloses that the amount of water soluble gelling gum in the composition is present at a level that provides a desired dissolution rate of said glassy matrix.

Beacause there is no teaching in Ream that the composition therein comprises a glassy matrix structure, or a water soluble gelling gum in an amount sufficient to provide a desired dissolution rate of said glassy matrix, Ream cannot be read to anticipate the present invention. Applicant respectfully requests withdrawal of this rejection.

35 USC §103

The Examiner rejects claims 1-33 under 35 USC §103 (a) as being obvious in light of Ventouras (US 6,183,775 B1) in view of Rapp et al. (US 6,180,143 B1, hereinafter "Rapp") or Burnick et al. (US2003/0017202 A1, hereinafter "Burnick"). Further, the Examiner rejects claims 10-21 in light of Ream. Applicant asserts that Ventouras, taken alone or in combination with either Rapp or Burnick does not render claims 1-33 obvious. Applicant further asserts that Claims 10-21 are not rendered obvious by Ream.

In order to establish a *prima facie* case of obviousness, three basic criteria must be established. First, there must be some suggestion or motivation to modify

the reference or combine the teachings. Second, there must be some reasonable expectation of success. Finally, the prior art reference(s) must teach each and every claim limitation. See MPEP §2143.

Applicant asserts that the Examiner has not established a *prima facie* case of obviousness with regard to Ventouras in combination with either Rapp or Burnick. In particular, there is no motivation or suggestion in Ventouras to modify the composition therein based on the teachings of Rapp or Burnick to achieve each and every element of the present invention. In fact, it can be said that Ventouras teaches *away* from the present invention.

Ventouras relates to a controlled release lozenge comprising an insoluble matrix for delivery of an active substance. Ventouras requires three essential components, a soluble filler, an insoluble film forming agent, and a swellable polymer. At column 3, line 51-60, Ventouras teaches that a composition comprising only a soluble filler in combination with a swellable polymer, formed by compression, results in a lozenge with unpleasant organoleptics. In other words, Ventouras teaches that the formulations therein must comprise both a swellable polymer as well as an insoluble film forming agent (in addition to the soluble filler) in order to achieve the desired formulation.

The Examiner cites Rapp and Burnick for the principle that sweetening agents, such as Isomalt, are known for use in nicotine formulations. Rapp relates to chewing gum compositions which may comprise 1,1-GPS alone or in combination with other sweeteners. Such sweeteners are incorporated into the Rapp compositions to increase flexibility of the gum and prevent drying out of the gum during storage. Burnick relates to an oral dosage form comprising a soft core encased within a brittle shell coating that also my include sweeteners of the type described above.

In contrast, the formulations of the present invention comprise a glassy matrix of a non-hygroscopic sugar alcohol and a water soluble gelling gum resulting in an oral dosage form suitable for transmucosal delivery of an active agent. The formulations of the present invention are prepared as if hard glassy confections, e.g. hard boiled confections, and not formed by compression as the formulations in Ventouras.

Clearly, neither Rapp nor Burnick relates to an oral dosage form comprising a glassy matrix of a non-hygroscopic sugar alcohol, as a glassy matrix would not provide an acceptable chewing gum or chewable soft core composition. Further, because Ventouras teaches away from the oral dosage forms of the present invention, there is no motivation to combine the teaching in Rapp or Burnick with the teaching of Ventouras. None of the references cited relate to an oral dosage form comprising a glassy matrix suitable for delivering an active agent at a desired oral dissolution rate comprising at least one non-hygroscopic sugar alcohol and a water soluble gelling gum.

Further, the Examiner rejects claims 10-21 under 35 USC §103 (a) as being obvious in light of Ream. The Examiner indicates that Ream does not disclose the amount of gum present in the compositions therein, however, asserts that such a difference will not support patentability unless there is evidence that the amount or concentration of the gum is critical. However, Application asserts that the Ream reference must be taken as a whole and must suggest the desirability and thus the obviousness of making the modification proposed by the Examiner. See *Hodosh v. Block Drug Co., Inc.,* 786 F2d 1136, 1143 (Fed Cir. 1986).

As stated above, Ream does not teach each and every element of the claimed invention. Ream relates to a chewing gum composition comprising a tabletted gum center and a coating, suitable for delivering a medicament or agent to an individual. The tabletted gum center comprises a water soluble portion and a water insoluble portion.

Ream cannot be said to suggest that a non-hygroscopic sugar alcohol may be prepared as a *glassy matrix* suitable for oral dissolution, as this directly conflicts with the goal of Ream, i.e. to achieve a suitable chewing gum composition. Further, Ream does not contemplate a composition comprising a water soluble gelling gum *present at a level that provides a desired dissolution rate of said glassy matrix.* In Ream, guar gum hydrosylate may optionally be incorporated as a bulking agent where a low calorie gum is desired. There is no teaching or suggestion that water soluble gelling gums are suitable for modifying the dissolution rate of a non-hygroscopic sugar alcohol glassy matrix.

Applicant respectfully requests that the Examiner's rejections based on 35 USC §103(a) in light of Ventouras in combination with Rapp or Burnick, or in light of Ream taken alone, be withdrawn. The Examiner has failed to establish the basic requirements of a prima facie case of obviousness

Double Patenting

The Examiner has provisionally rejected claims 1-33 under 35 USC 101 as claiming the same invention as that of claims 1-33 of copending Application No. 10/244,782. Application No. 10/244,782 has been expressly abandoned and a copy of said express abandonment files is included herewith.

The Examiner has provisionally rejected claim 33 under 35 USC 101 as claiming the same invention as that of claim 52 of copending Application No. 10/471,477. In response, Applicant has herein cancelled claim 33.

The Examiner has provisionally rejected claims 1, 3 and 13-32 under the judicially created doctrine of obviousness-type double patenting. In response, Applicant encloses herewith a terminal disclaimer

Respectfully submitted,

Andrea L. Winslow

Andrea L. Winslow
Attorney for Applicants
Registration No. 48,586

GLAXOSMITHKLINE
Corporate Intellectual Property-UW2220
P.O. Box 1539
King of Prussia, PA 19406-0939
Tel: 610 270 7513
Fax: 610 270 5090
Email: Andrea.L.Winslow@gsk.com

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